

REMARKS

Apparatus claims 1 to 14 have been canceled. Claims 15 to 20 were previously canceled.

Independent method claim 21 has been amended. Dependent method claims 22 to 24 have also been amended to reflect the language of the independent claim 21.

Claims 21 to 24 remain in the application.

Reexamination and reconsideration are respectfully requested in view of the amendments and the remarks that follow.

Claim 21 has been amended to define a method for supplementing, repairing, or replacing a native heart valve leaflet or leaflets. The method comprises selecting a native heart valve having an annulus, native heart valve leaflets, and generally opposite leaflet commissures spaced apart by a maximum cross-annulus distance defining a major axis of the annulus. As further defined in amended claim 21, the method provides an implant comprising an elastic scaffold carrying a neoleaflet element. The elastic scaffold comprises a normal, unloaded condition including a spring constant to undergo compression during use in response to applied external compression forces into an elastically loaded condition. As further defined in amended claim 21, the implant further comprises at least two struts coupled to the elastic scaffold in generally oppositely spaced apart positions defining, when the elastic scaffold is in the normal, unloaded condition, a normal cross-strut distance that is greater than the maximum cross-annulus distance.

As further defined in amended claim 21, the method introduces the implant into a heart with the elastic scaffold in the normal, unloaded condition. The method applies external compression forces at the at least two struts to reduce the normal cross-strut distance to place the elastic scaffold into the elastically loaded condition. While the elastic scaffold is in the elastically loaded condition, the method places the struts into engagement with tissue at or near the leaflet commissures, to apply tension and outwardly displace and separate tissue along the major axis of the annulus to reshape the annulus for leaflet coaptation.

As further defined in amended claim 21, while the struts are placed in engagement with tissue at or near the leaflet commissures, the method provides a one-way valve function with the neoleaflet element that, in response to a first pressure condition, assumes the valve opened

condition and, in response to second pressure condition, assumes the valve closed condition. Also, the struts brace the elastic scaffold, while in the elastically loaded condition, against migration within the annulus during the one-way valve function.

Claims 21 to 24 stand rejected under 35 U.S.C. § 102(e) based upon DiMatteo (US 6,685,739). DiMatteo does not teach or suggest a method, as defined in amended claim 21, for supplementing, repairing, or replacing a native heart valve leaflet or leaflets. For example, (i) DiMatteo does not teach or suggest the introduction of an implant comprising an elastic scaffold comprising a normal, unloaded condition including a spring constant to undergo compression in response to applied external compression forces into an elastically loaded condition; (ii) DiMatteo does not teach or suggest at least two struts coupled to the elastic scaffold in generally oppositely spaced apart positions defining, when the elastic scaffold is in the normal, unloaded condition, a normal cross-strut distance that is greater than the maximum cross-annulus distance; and (iii) DiMatteo does not teach or suggest introducing an implant into a heart with the elastic scaffold in the normal, unloaded condition, and applying external compression forces at the at least two struts to reduce the normal cross-strut distance to place the elastic scaffold into the elastically loaded condition, and while the elastic scaffold is in the elastically loaded condition, placing the struts into engagement with tissue at or near the leaflet commissures, to apply tension and outwardly displace and separate tissue along the major axis of the annulus to reshape the annulus for leaflet coaptation.

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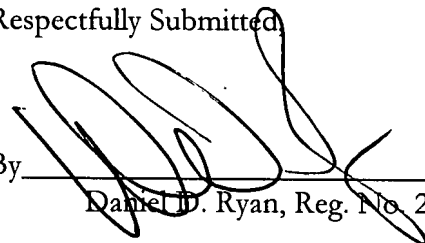
Amendment B

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Claims 21 to 24 are therefore believed to be in condition for allowance.

Respectfully Submitted,

By

A handwritten signature in black ink, appearing to read 'Daniel D. Ryan', is written over a horizontal line.

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